General

Guideline Title

ACR Appropriateness Criteria® breast cancer screening.

Bibliographic Source(s)

Mainiero MB, Moy L, Baron P, Didwania AD, diFlorio-Alexander RM, Green ED, Heller SL, Holbrook AI, Lee SJ, Lewin AA, Lourenco AP, Nance KJ, Niell BL, Slanetz PJ, Stuckey AR, Vincoff NS, Weinstein SP, Yepes MM, Newell MS, Expert Panel on Breast Imaging. ACR Appropriateness CriteriaÂ® breast cancer screening. Reston (VA): American College of Radiology (ACR); 2017. 9 p. [65 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Mainiero MB, Bailey L, D'Orsi C, Green ED, Holbrook AI, Lee SJ, Lourenco AP, Moy L, Sepulveda KA, Slanetz PJ, Trikha S, Yepes MM, Newell MS, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® breast cancer screening. Reston (VA): American College of Radiology (ACR); 2016. 7 p. [52 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests

	Guideline Development Group Composition
YES	Multidisciplinary Group
YES	Methodologist Involvement
▮▯▯▯▯	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▮	Search Strategy
▮▮▮▯▯	Study Selection
▮▮▮▮▯	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▯▯▯	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▯	Evidence Summary Supporting Recommendations
▮▮▮▮▯	Rating the Strength of Recommendations
▮▮▮▮▮	Specific and Unambiguous Articulation of Recommendations
▮▯▯▯▯	External Review
▮▮▮▯▯	Updating

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Breast Cancer Screening

Variant 1: Breast cancer screening. Average-risk women: women with <15% lifetime risk of breast cancer.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography screening	Usually Appropriate	☢☢
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
US breast	May Be Appropriate	O
MRI breast without and with IV contrast	Usually Not Appropriate	O
MRI breast without IV contrast	Usually Not Appropriate	O

Procedure	Appropriateness Category	Relative Radiation Level
FDG-PEM	Usually Not Appropriate	☢☢☢☢
Tc-99m sestamibi MBI	Usually Not Appropriate	☢☢☢

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Breast cancer screening. Intermediate-risk women: women with personal history of breast cancer, lobular neoplasia, atypical ductal hyperplasia, or 15% to 20% lifetime risk of breast cancer.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography screening	Usually Appropriate	☢☢
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
MRI breast without and with IV contrast	May Be Appropriate	O
US breast	May Be Appropriate	O
FDG-PEM	Usually Not Appropriate	☢☢☢☢
Tc-99m sestamibi MBI	Usually Not Appropriate	☢☢☢
MRI breast without IV contrast	Usually Not Appropriate	O

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Breast cancer screening. High-risk women: women with a BRCA gene mutation and their untested first-degree relatives, women with a history of chest irradiation between 10 to 30 years of age, women with 20% or greater lifetime risk of breast cancer.

Procedure	Appropriateness Category	Relative Radiation Level
Mammography screening	Usually Appropriate	☢☢
Digital breast tomosynthesis screening	Usually Appropriate	☢☢
MRI breast without and with IV contrast	Usually Appropriate	O
US breast	May Be Appropriate	O
FDG-PEM	Usually Not Appropriate	☢☢☢☢
Tc-99m sestamibi MBI	Usually Not Appropriate	☢☢☢
MRI breast without IV contrast	Usually Not Appropriate	O

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction/Background

Other than skin cancer, breast cancer is the most common cancer diagnosis and the second leading cause of cancer death in women. Since the advent of screening mammography in the United States, breast cancer mortality has decreased 36% between 1989 and 2012, after slowly increasing before that time. Long-term follow-up analysis of populations before and after the institution of screening mammography attributes the decrease in mortality to screening of the general population. In addition to mortality reduction, early detection allows for a wider range of less invasive treatment options.

The sensitivity of mammography is dependent upon breast density, where sensitivity decreases with the increase of breast density. Breast density is reported on mammography as: A = "almost entirely fatty," B = "scattered areas of fibroglandular density," C = "heterogeneously dense," or D = "extremely dense,"

where "heterogeneously dense" and "extremely dense" (C and D categories) are considered dense.

Discussion of Procedures by Variant

Variant 1: Breast Cancer Screening. Average-risk Women: Women with <15% Lifetime Risk of Breast Cancer

Mammography and DBT

In follow-up of randomized controlled trials of screening mammography in women 40 to 74 years of age, there continues to be a highly significant decrease in mortality in those randomized to invitation to screening mammography. Because breast cancer incidence increases with age, more women among the younger age group (40-50) will need to be screened for each life saved than for women 50 years of age or older. However, because younger women have a longer life expectancy, life years gained for the women diagnosed with breast cancer by screening in their 40s is higher than in the 50- to 70-year-old population. The age at which various organizations recommend beginning screening mammography and the frequency at which mammography is recommended in different age groups varies based upon the weight given to the perceived risks (false-positive examinations and the possibility of over-diagnosis) and benefits of screening (mortality reduction and less invasive treatment options). Some groups recommend screening for all women starting at age 50, with screening recommended between 40 to 50 years of age dependent upon patient preference or risk. However, personalized screening in the 40 to 49 year age group would cause the majority of screen-detected cancers to be excluded from detection. Groups also vary on whether screening mammography is recommended as an annual or biennial examination. Based on a review of the randomized trials and subsequent meta-analyses, the ACR recommends annual screening beginning at 40 years of age. There is no upper age limit established for screening mammography, but as the benefits of screening mammography may take years to be fully realized, screening recommendations should take into account life expectancy and comorbid conditions, with screening mammography remaining appropriate when a woman's life expectancy exceeds 5 to 7 years.

Digital breast tomosynthesis (DBT) can address some of the limitations encountered with standard mammographic views. In addition to planar images, DBT allows for creation and viewing of thin-section reconstructed images that may decrease the lesion-masking effect of overlapping normal tissue and reveal the true nature of potential false-positive findings without the need for recall. Several studies confirm that in a screening setting, the cancer detection rate is increased with use of DBT compared with 2-D mammography alone. Additionally, the rate of recall for benign findings (false-positives) can be decreased. Some authors found these advantages to be especially pronounced in women under age 50, in those with dense breasts, and with lesion types including spiculated masses and asymmetries. Interpretation time for DBT images is greater than for standard mammography. Additionally, dose is increased if standard 2-D images are obtained in addition to DBT images. However, synthesized reconstructed images (a virtual planar image created from the tomographic dataset) may replace the need for a 2-D correlative view; current data suggest that these synthetic images perform as well as standard full-field digital images. DBT is almost always performed as part of an examination that also includes digital mammography. The digital mammography part of the examination may be in the form of traditional projection mammography or synthesized image from the DBT data.

US

The presence of dense breast tissue lowers the sensitivity of mammography and increases breast cancer risk when compared with patients with fatty breasts. Adding hand-held or automated breast ultrasound (US) to mammography in women with dense breasts increases the cancer detection rate but also substantially increases the false-positive rate. In the initial clinical experience with screening breast US after a dense breast notification law was enacted on a state-wide level, the cancer detection rate increased but the number of short interval follow-up recommendations increased substantially and the positive predictive value of a biopsy recommendation was much lower. For women with dense breasts tissue but no additional risk factors, US may be useful as an adjunct to mammography for incremental cancer detection, but the balance between increased cancer detection and the increased risk of a false-positive examination should be considered in the decision. There are no data to support the use of US for

average-risk women with nondense breasts.

MBI and FDG-PEM

Supplementing mammography with molecular breast imaging (MBI) in women with dense breasts increases the cancer detection rate. However, there have been no large population studies of MBI for screening, and the whole-body radiation dose with this technique is concerning. Positron emission mammography with fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG-PEM) is similarly limited by radiation dose and lack of evidence in large screening populations.

MRI

There is insufficient evidence to support the use of magnetic resonance imaging (MRI) for screening women of average risk.

Variant 2: Breast Cancer Screening. Intermediate-risk Women: Women with Personal History of Breast Cancer, Lobular Neoplasia, Atypical Ductal Hyperplasia, or 15% to 20% Lifetime Risk of Breast Cancer

Some women with an intermediate risk of breast cancer may benefit by beginning screening mammography earlier than 40 years of age and may also benefit from supplemental screening. The recommendations for supplemental screening for women at intermediate risk of breast cancer, including those with a personal history of breast cancer, a history of lobular carcinoma in situ or ADH, those with an intermediate family history and a lifetime risk of 15% to 20%, or women with dense breasts continues to be an area of debate.

Mammography and DBT

Annual screening mammography is recommended for women with biopsy-proven lobular neoplasia or atypical ductal hyperplasia beginning at diagnosis, but not when <30 years of age. Women who have a prior history of breast cancer are recommended to have mammography every 12 months (and 6 to 12 months post-radiation if the breast is conserved).

The sensitivity of mammography is dependent upon breast density, with sensitivity decreasing with increasing breast density. DBT can address some of the limitations encountered with standard mammographic views. In addition to planar images, DBT allows for creation and viewing of thin-section reconstructed images that can decrease the lesion-masking effect of overlapping normal tissue and reveal the true nature of potential false-positive findings without the need for recall. Several studies confirm that in a screening setting, cancer detection rate is increased with the use of DBT compared to 2-D mammography alone. Additionally, the rate of recall for benign findings (false-positives) can be decreased. Some authors found these advantages to be especially pronounced in women under age 50, in those with dense breasts, and with lesion types including spiculated masses and asymmetries. Interpretation time for DBT images is greater than for standard mammography. Additionally, dose is increased if standard 2-D images are obtained in addition to DBT images. However, synthesized reconstructed images (a virtual planar image created from the tomographic dataset) may replace the need for a 2-D correlative view; current data suggest that these synthetic images perform as well as standard full-field digital images. DBT is almost always performed as part of an examination that also includes digital mammography. The digital mammography part of the examination may be in the form of traditional projection mammography or synthesized from the DBT data.

US

In women with dense breasts and increased risk of breast cancer, mammography sensitivity can be as low as 50%; supplementing mammography screening with US will significantly increase cancer detection, although false-positive rates are also substantially increased. In intermediate-risk women with dense breasts, supplemental US screening is an option.

MRI

The American Cancer Society considers there to be insufficient evidence for or against MRI as an adjunct

to mammography in women at intermediate risk of breast cancer. However, recent studies support the use of screening MRI in certain subsets of this population, including women with a history of lobular carcinoma in situ or a personal history of breast cancer.

MBI and FDG-PEM

Supplementing mammography with MBI in women with dense breasts increases the cancer detection rate. However, there have been no large population studies of MBI for screening and whole body radiation dose with this technique is concerning. FDG-PEM is similarly limited by radiation dose and lack of evidence in large screening populations.

Variant 3: Breast Cancer Screening. High-risk Women: Women with a BRCA Gene Mutation and Their Untested First-degree Relatives, Women with a History of Chest Irradiation Between 10 to 30 Years of Age, Women with 20% or Greater Lifetime Risk of Breast Cancer

Women at high risk for breast cancer include those with BRCA or other known genetic predispositions, women with a very strong family history placing them at more than a 20% lifetime risk of breast cancer, and those with prior mantle radiation therapy between 10 to 30 years of age. In addition to beginning screening mammography earlier than the general population, women in this high-risk group benefit from supplemental screening.

Mammography and DBT

Annual mammography is recommended starting 8 years after radiation therapy but not before age 25 for women who received mantle radiation between 10 to 30 years of age. As there is some concern about young women with an inherited cancer predisposition having increased sensitivity to radiation, women with a genetic predisposition are recommended for annual screening beginning 10 years earlier than the affected relative at the time of diagnosis but not before age 30.

The sensitivity of mammography is dependent upon breast density, with sensitivity decreasing with increasing breast density. DBT can address some of the limitations encountered with standard mammographic views. In addition to planar images, DBT allows for creation and viewing of thin-section reconstructed images that may decrease the lesion-masking effect of overlapping normal tissue and reveal the true nature of potential false-positive findings without the need for recall. Several studies confirm that in a screening setting, the cancer detection rate is increased with use of DBT compared to 2-D mammography alone. Additionally, the rate of recall for benign findings (false-positives) can be decreased. Some authors found these advantages to be especially pronounced in women under age 50, in those with dense breasts, and those with lesion types including spiculated masses and asymmetries. Interpretation time for DBT images is greater than for standard mammography. Additionally, dose is increased if standard 2-D images are obtained in addition to DBT images. However, synthesized reconstructed images (a virtual planar image created from the tomographic dataset) may replace the need for a 2-D correlative view; and current data suggest that these synthetic images perform as well as standard full-field digital images. DBT is almost always performed as part of an examination that also includes digital mammography. The digital mammography part of the examination may be in the form of traditional projection mammography or synthesized image from the DBT data.

MRI

Breast MRI in high-risk women has a higher sensitivity than mammography, and the combination of mammography and MRI in this population has the highest sensitivity. In a high-risk population, MRI and mammography combined have a higher sensitivity (92.7%) than US and mammography combined (52%). Therefore, in high-risk women for whom supplemental screening is indicated, MRI is recommended when possible. Screening MRI is recommended in women with BRCA gene mutations and their untested first-degree relatives as well as women with a lifetime risk of breast cancer of ~20% or greater. Also included in this high-risk group are women who have received radiation therapy to the chest between 10 to 30 years of age as well as women with other genetic syndromes that increase the risk of breast cancer.

Screening high-risk women with breast MRI is cost-effective, and the cost-effectiveness of screening MRI

increases with increasing breast cancer risk. The American Cancer Society recommends breast-screening MRI in high-risk women, and the ACR and the Society of Breast Imaging endorse those recommendations.

US

Screening US is indicated in high-risk patients who cannot tolerate MRI. Mammography alone does not perform as well as mammography plus supplemental screening in high-risk women, especially those with a genetic predisposition, and supplemental screening US is indicated in high-risk patients who cannot tolerate MRI.

MBI and FDG-PEM

Supplementing mammography with MBI in women with dense breasts increases the cancer detection rate. However, there have been no large population studies of MBI for screening and the whole-body radiation dose with this technique is concerning. FDG-PEM is similarly limited by radiation dose and lack of evidence in large screening populations.

Summary of Recommendations

For average-risk women, annual screening mammography or DBT (with accompanying planar or synthesized 2-D images) is recommended beginning at age 40. For women with dense breasts, US may also be considered, but the balance between increased cancer detection and the increased risk of a false-positive examination should be considered in the decision.
For intermediate-risk women, breast mammography or DBT (with accompanying planar or synthesized 2-D images) is recommended. MRI may be considered as an adjunct to mammography or DBT (with accompanying planar or synthesized 2-D images) depending upon risk factors. For women with dense breasts, US may be an option, but the balance between increased cancer detection and the increased risk of a false-positive examination should be considered in the decision.
For high-risk women, mammography or DBT (with accompanying planar or synthesized 2-D images) is recommended. MRI is recommended as an adjunct to screening mammography or DBT (with accompanying planar or synthesized 2-D images). US is recommended when the patient cannot tolerate MRI.

Abbreviations

BRCA, BReast CAncer 1 gene
FDG-PEM, fluorine-18-2-fluoro-2-deoxy-D-glucose positron-emission mammography
IV, intravenous
MRI, magnetic resonance imaging
Tc-99m, technetium-99 metastable
US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
☢	<0.1 mSv	<0.03 mSv
☢☢	0.1-1 mSv	0.03-0.3 mSv
☢☢☢	1-10 mSv	0.3-3 mSv
☢☢☢☢	10-30 mSv	3-10 mSv
☢☢☢☢☢	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."		

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Breast cancer

Guideline Category

Prevention

Screening

Clinical Specialty

Family Practice

Internal Medicine

Nuclear Medicine

Obstetrics and Gynecology

Oncology

Preventive Medicine

Radiology

Intended Users

Advanced Practice Nurses

Health Care Providers

Hospitals

Managed Care Organizations

Physician Assistants

Physicians

Students

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of imaging procedures for breast cancer screening

Target Population

Women at high, intermediate, and average risk of breast cancer

Interventions and Practices Considered

1. Mammography screening
2. Digital breast tomosynthesis screening
3. Magnetic resonance imaging (MRI), breast
    - Without and with intravenous (IV) contrast
    - Without IV contrast
4. Ultrasound (US), breast
5. Fluorine-18-2-fluoro-2-deoxy-D-glucose positron-emission mammography (FDG-PEM)
6. Technetium-99 metastable (Tc-99m) sestamibi breast-specific gamma imaging (BSGI)

Major Outcomes Considered

- Breast cancer mortality
- Breast cancer detection rate
- False-positive rates
- Diagnostic accuracy, sensitivity, and specificity of imaging procedures for breast cancer diagnosis
- Recall rates
- Radiation dose

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Summary

Of the 65 citations in the original bibliography, 14 were retained in the final document.

A new literature search was conducted in December 2015 and updated on March 2016 to identify additional evidence published since the *ACR Appropriateness Criteria® Breast Cancer Screening* topic was finalized. Using the search strategy described in the literature search companion (see the "Availability of Companion Documents" field), 379 articles were found. Twenty-four articles were added to the bibliography. The remaining articles were not used due to either poor study design, the articles were not relevant or generalizable to the topic, the results were unclear, misinterpreted, or biased, or the articles were already cited in the original bibliography.

The author added 27 citations from bibliographies, Web sites, or books that were not found in the new literature search.

See also the American College of Radiology (ACR) Appropriateness Criteria® literature search process document (see the "Availability of Companion Documents" field) for further information.

Number of Source Documents

Of the 65 citations in the original bibliography, 14 were retained in the final document. The new literature search conducted in December 2015 and updated on March 2016 found 24 articles that were added to the bibliography. The author added 27 citations from bibliographies, Web sites, or books that were not found in the new literature search.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Definitions of Study Quality Categories

Category 1 - The study is well-designed and accounts for common biases.

Category 2 - The study is moderately well-designed and accounts for most common biases.

Category 3 - The study has important study design limitations.

Category 4 - The study or source is not useful as primary evidence. The article may not be a clinical study, the study design is invalid, or conclusions are based on expert consensus.

> The study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description);
>
> *Or*
>
> The study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence;
>
> *Or*
>
> The study is an expert opinion or consensus document.

Category M - Meta-analysis studies are not rated for study quality using the study element method because the method is designed to evaluate individual studies only. An "M" for the study quality will indicate that the study quality has not been evaluated for the meta-analysis study.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author assesses the literature then drafts or revises the narrative summarizing the evidence found in the literature. American College of Radiology (ACR) staff drafts an evidence table based on the analysis of the selected literature. These tables rate the study quality for each article included in the narrative.

The expert panel reviews the narrative, evidence table and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the variant table(s). Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Overview

The purpose of the rating rounds is to systematically and transparently determine the panels' recommendations while mitigating any undue influence of one or more panel members on another individual panel members' interpretation of the evidence. The panel member's rating is determined by reviewing the evidence presented in the Summary of Literature Review and assessing the risks or harms of performing the procedure or treatment balanced with the benefits of performing the procedure or treatment. The individual panel member ratings are used to calculate the median rating, which determines the panel's rating. The assessment of the amount of deviation of individual ratings from the panel rating determines whether there is disagreement among the panel about the rating.

The process used in the rating rounds is a modified Delphi method based on the methodology described in the RAND/UCLA Appropriateness Method User Manual.

The appropriateness is rated on an ordinal scale that uses integers from 1 to 9 grouped into three categories (see the "Rating Scheme for the Strength of the Recommendations" field).

Determining the Panel's Recommendation

> Ratings represent an individual's assessment of the risks and benefits of performing a specific procedure for a specific clinical scenario on an ordinal scale. The recommendation is the appropriateness category (i.e., "Usually appropriate," "May be appropriate," or "Usually not appropriate").
>
> The appropriateness category for a procedure and clinical scenario is determined by the panel's median rating without disagreement (see below for definition of disagreement). The panel's median rating is calculated after each rating round. If there is disagreement after the second rating round, the rating category is "May be appropriate (Disagreement)" with a rating of "5" so users understand the group disagreed on the final recommendation. The actual panel median rating is documented to provide additional context.
>
> Disagreement is defined as excessive dispersion of the individual ratings from the group (in this case, an Appropriateness Criteria [AC] panel) median as determined by comparison of the interpercentile range (IPR) and the interpercentile range adjusted for symmetry (IPRAS). In those instances when the IPR is greater than the IPRAS, there is disagreement. For a complete discussion, please refer to chapter 8 of the RAND/UCLA Appropriateness Method User Manual.
>
> Once the final recommendations have been determined, the panel reviews the document. If two thirds of the panel feel a final recommendation is wrong (e.g., does not accurately reflect the evidence, may negatively impact patient health, has unintended consequences that may harm health care, etc.) and the process must be started again from the beginning.

For additional information on the ratings process see the Rating Round Information document (see the "Availability of Companion Documents" field).

Additional methodology documents, including a more detailed explanation of the complete topic development process and all ACR AC topics can be found on the ACR Web site (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

Cost Analysis

Screening high-risk women with breast magnetic resonance imaging (MRI) is cost effective and the cost-effectiveness of screening MRI increases with increasing breast cancer risk.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current medical evidence literature and the application of the RAND/UCLA appropriateness method and expert panel consensus.

Summary of Evidence

Of the 65 references cited in the *ACR Appropriateness Criteria® Breast Cancer Screening* document, all of them are categorized as diagnostic references including 12 well-designed studies, 12 good-quality studies, and 22 quality studies that may have design limitations. There are 18 references that may not be useful as primary evidence. There is one reference that is a meta-analysis study.

While there are references that report on studies with design limitations, 24 well-designed or good-quality studies provide good evidence.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- The age at which various organizations recommend beginning screening mammography and the frequency at which mammography is recommended in different age groups varies based upon the weight given to the perceived risks (false-positive examinations and the possibility of over-diagnosis) and benefits of screening (mortality reduction and less invasive treatment options).
- Digital breast tomosynthesis (DBT) can address some of the limitations encountered with standard mammographic views. In addition to planar images, DBT allows for creation and viewing of thin-section reconstructed images that may decrease the lesion-masking effect of overlapping normal tissue and reveal the true nature of potential false-positive findings without the need for recall. Several studies confirm that in a screening setting, cancer detection rate is increased with use of digital breast tomosynthesis (DBT) compared to two-dimensional (2-D) mammography alone. Additionally, the rate of recall for benign findings (false positives) can be decreased. Some authors found these advantages to be especially pronounced in women under age 50, in those with dense breasts, and with lesion types including spiculated masses and asymmetries.
- Breast magnetic resonance imaging (MRI) in high-risk women has a higher sensitivity than mammography, and the combination of mammography and MRI in this population has the highest sensitivity. In a high-risk population, MRI and mammography combined have a higher sensitivity (92.7%) than ultrasound (US) and mammography combined (52%). Screening high-risk women with breast MRI is cost-effective and the cost-effectiveness of screening MRI increases with increasing breast cancer risk.

Potential Harms

- The age at which various organizations recommend beginning screening mammography and the frequency at which mammography is recommended in different age groups varies based upon the weight given to the perceived risks (false-positive examinations and the possibility of over-diagnosis) and benefits of screening (mortality reduction and less invasive treatment options).
- The presence of dense breast tissue lowers the sensitivity of mammography and increases breast cancer risk when compared with patients with fatty breasts. Adding hand-held or automated breast ultrasound (US) to mammography in women with dense breasts increases the cancer detection rate but also substantially increases the false-positive rate.

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Qualifying Statements

Qualifying Statements

- The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.
- ACR seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria through society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply society endorsement of the final document.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Mainiero MB, Moy L, Baron P, Didwania AD, diFlorio-Alexander RM, Green ED, Heller SL, Holbrook AI, Lee SJ, Lewin AA, Lourenco AP, Nance KJ, Niell BL, Slanetz PJ, Stuckey AR, Vincoff NS, Weinstein SP, Yepes MM, Newell MS, Expert Panel on Breast Imaging. ACR Appropriateness CriteriaÂ® breast cancer screening. Reston (VA): American College of Radiology (ACR); 2017. 9 p. [65 references]

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Not applicable: The guideline was not adapted from another source.

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Guideline Developer(s)

American College of Radiology - Medical Specialty Society

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The funding for the process is assumed entirely by the American College of Radiology (ACR). ACR staff support the expert panels through the conduct of literature searches, acquisition of scientific articles, drafting of evidence tables, dissemination of materials for the Delphi process, collation of results, conference calls, document processing, and general assistance to the panelists.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Breast Imaging

Composition of Group That Authored the Guideline

Panel Members: Martha B. Mainiero, MD (*Principal Author*); Linda Moy, MD (*Panel Vice-chair*); Paul Baron, MD; Lisa Bailey, MD; Aarati D. Didwania, MD; Roberta M. diFlorio-Alexander, MD; Edward D. Green, MD; Samantha L. Heller, MD; Anna I. Holbrook, MD; Su-Ju Lee, MD; Alana A. Lewin, MD; Ana P. Lourenco, MD; Kara J. Nance, MD; Bethany L. Niell, MD; Priscilla J. Slanetz, MD, MPH; Ashley R. Stuckey, MD; Nina S. Vincoff, MD; Susan P. Weinstein, MD; Monica M. Yepes, MD; Mary S. Newell, MD (*Panel Chair*)

Financial Disclosures/Conflicts of Interest

Disclosing Potential Conflicts of Interest and Management of Conflicts of Interest

An important aspect of committee operations is the disclosure and management of potential conflicts of interest. In 2016, the American College of Radiology (ACR) began an organization-wide review of its conflict of interest (COI) policies. The current ACR COI policy is available on its Web site. The Appropriateness Criteria (AC) program's COI process varies from the organization's current policy to accommodate the requirements for qualified provider-led entities as designated by the Centers for Medicare and Medicaid Services' Appropriate Use Criteria (AUC) program.

When physicians become participants in the AC program, welcome letters are sent to inform them of their panel roles and responsibilities, including a link to complete the COI form. The COI form requires disclosure of all potential conflicts of interest. ACR staff oversees the COI evaluation process, coordinating with review panels consisting of ACR staff and members, who determine when there is a conflict of interest and what action, if any, is appropriate. In addition to making the information publicly available, management may include exclusion from some topic processes, exclusion from a topic, or exclusion from the panel.

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Finally, all ACR AC are published as part of the Journal of the American College of Radiology (JACR) electronic supplement. Those who participated on the document and are listed as authors must complete the JACR process that includes completing the International Committee of Medical Journal Editors (ICMJE) COI form which is reviewed by the journal's staff/publisher.

Dr. Slanetz reports author or co-author on three active topics (breast MRI and emerging technologies; breast cancer screening; and imaging of dense breasts. Royalties based on usage by membership, approximately $1500 per year. The other authors have no conflicts of interest related to the material discussed in this article.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Mainiero MB, Bailey L, D'Orsi C, Green ED, Holbrook AI, Lee SJ, Lourenco AP, Moy L, Sepulveda KA, Slanetz PJ, Trikha S, Yepes MM, Newell MS, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® breast cancer screening. Reston (VA): American College of Radiology (ACR); 2016. 7 p. [52 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the American College of Radiology (ACR) Web site .

Availability of Companion Documents

The following are available:

ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2017. Available from the American College of Radiology (ACR) Web site .
ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2015 Feb. 1 p. Available from the ACR Web site .
ACR Appropriateness Criteria®. Evidence table development. Reston (VA): American College of Radiology; 2015 Nov. 5 p. Available from the ACR Web site .
ACR Appropriateness Criteria®. Topic development process. Reston (VA): American College of Radiology; 2015 Nov. 2 p. Available from the ACR Web site .
ACR Appropriateness Criteria®. Rating round information. Reston (VA): American College of Radiology; 2017 Sep. 5 p. Available from the ACR Web site .
ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2018. 4 p. Available from the ACR Web site .
ACR Appropriateness Criteria®. Manual on contrast media. Reston (VA): American College of Radiology; 2017. 125 p. Available from the ACR Web site .
ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 2017 Mar. 4 p. Available from the ACR Web site .
ACR Appropriateness Criteria® breast cancer screening. Evidence table. Reston (VA): American College of Radiology; 2017. 41 p. Available from the ACR Web site .
ACR Appropriateness Criteria® breast cancer screening. Literature search summary. Reston (VA): American College of Radiology; 2017. 2 p. Available from the ACR Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on August 21, 2012. The guideline developer agreed to not review the content. This summary was updated by ECRI Institute on September 14, 2016. The guideline developer agreed to not review the content. This summary was updated by ECRI Institute on May 14, 2018. The guideline developer agreed to not review the content.

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